The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED

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U.S. PAILNI AND IRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES Ex parte ANAND BAICHWAL and JOHN N. STANIFORTH

Appeal No. 2005-2588 Application No. 10/047,060

ON BRIEF

Before ELLIS, ADAMS, and GREEN, Administrative Patent Judges.

Opinion by GREEN, <u>Administrative Patent Judge</u>. Dissenting opinion by Ellis, <u>Administrative Patent Judge</u>.

VACATUR AND REMAND TO THE EXAMINER

On consideration of the record, we find that this case is not susceptible to meaningful review and is thus not in condition for a decision on appeal.

Accordingly, we vacate the pending rejections and remand the application to the examiner to consider the issues discussed herein and take appropriate action not inconsistent with the views expressed herein. Lest there be any misunderstanding, the term "vacate" in this context means to set aside or void.

When the Board vacates an examiner's rejection, the rejection is set aside and

no longer exists. <u>Cf. Ex parte Zambrano</u>, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2001).

BACKGROUND

The claims are drawn to a device for delivering a medicament to a patient.

Claims 26-43 are pending, claims 26 and 43 are representative of the claims on appeal.

26. A device for delivering a medicament to a patient, comprising an output port defining a passage for dispensing controlled release particles of a cohesive composite of a medicament and a pharmaceutically acceptable carrier to a patient;

a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter;

an actuator coupled to the chamber, the actuator selectively causing the cohesive composite particles to be dispensed to the patient through the passage of the output port.

43. A device for delivering a medicament to a patient, comprising a cohesive composite of a medicament together with a pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter

means for delivering the cohesive composite to a nasal or oral orifice.

Claims 26-43 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. In addition, claims 26-43

stand rejected under 35 U.S.C. § 102(b) as being anticipated by Evans¹ or Burns.²

VACATUR AND REMAND

The board serves as a board of review, not a <u>de novo</u> examination tribunal. <u>See</u> 35 U.S.C. § 6(b) ("The [board] shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents."). The burden is on the examiner to set forth a <u>prima facie</u> case of nonpatentability. <u>See In re Alton</u>, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996).

Claims 26-43 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention.

According to the rejection,

The claims lack any device limitations which would particularly point out the claimed invention. Applicant is attempting to limit the device through the use of a claimed composition only. The claims are therefore indefinite in that they do not distinctly claim a device by any limitations other than those which comprise an output port, a chamber and an actuator. The composition limitations do not particularly point out the claimed device. Clarification is required.

Final Rejection, dated February 26, pages 4-5.

Claims 26-43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Evans or Burns.

¹ Evans, U.S. Patent No. 5,239,993, issued August 31, 1993.

² Burns et al. (Burns), U.S. patent No. 5,284,133, issued February 8, 1994.

According to the rejection over Evans,

Evans [] disclose[s] a device for delivering medicament to a patient comprising an output port, a chamber, and an actuator which propels the medicament through the output port (see Abstract; Figure 3; and claims). The method of treating a patient by inhalation is disclosed at col. 1, lines 1-18. Composition limitations can not be used to define the claimed device over that of the prior art. Further, the claims lack any device limitations. The instant claims sets out a device which is clearly anticipated by [] Evans [].

<u>ld.</u> at 5.

With respect to the rejection over Burns, the examiner states:

Burns [] disclose[s] a device which comprises an output port, an actuator, and a chamber (see Figure 4A; col. 7, lines 40-62; and claims). The method of delivery is disclosed at col. 5, lines 47 et seq; and cols 6-7. Composition limitations can not be used to define the claimed device over the prior art. Further, the claims lack any device limitations. The instant claims are clearly anticipated by Burns [].

<u>Id.</u> at 5-6.

The examiner's rejections appear to be based on his unease with the combination required by the claim, that is, the combination of a device, an inhaler, and the composition contained within that inhaler. The Court of Appeals for the Federal Circuit, our reviewing court, has held that a "hybrid claim," that is, a claim that is drawn to a product and a method of using that product, is indefinite under 35 U.S.C. 112, second paragraph, on the grounds that "the combination of two separate statutory classes of invention, a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the

apparatus later performs the claimed method of using the apparatus." IXPL Holdings, L.L.C. v. Amazon.com, Inc., 430 F.3d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005). We can not find any authority, however, and the examiner does not cite to any such authority, that a claim cannot be drawn to a device, in this case the inhaler, and the composition contained within that inhaler, which are both drawn to the same statutory class of invention, i.e., a product.

Thus, we find that the examiner's concerns recited in the rejection made under 35 U.S.C. 112, second paragraph, are baseless. To the extent that the examiner is concerned with the breadth of limitations drawn to the inhaler portion of the product, "breadth is not to be equated with indefiniteness." <u>In re Miller,</u> 441 F.2d 689, 693, 169 USPQ 597, 600 (CCPA 1971); <u>see also In re Hyatt,</u> 708 F.2d 712, 714-15, 218 USPQ 195, 197 (Fed. Cir. 1983).

With respect to the rejections under 35 U.S.C. 102(b), for the reasons stated above, the examiner is legally incorrect in his statement that "[c]omposition limitations can not be used to define the claimed device over that of the prior art." In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently, see In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997), and that includes the composition limitations.

The examiner's concerns may be due to the fact that the composition contained within the inhaler has already been patented. See Supplemental

Examiner's Answer, page 4 ("Applicant has already been granted a patent on the composition."). We understand that concern, and share in it, and in that regard we direct the examiner's attention to the "Other Issues" section of this opinion, infra. But because the rejections of record are premised on a misunderstanding of the applicable law, they are hereby vacated.

We have reviewed the opinion expressed by the dissent, but cannot agree with it. The dissent appears to have the same concern as does the examiner, i.e., that the claims to the composition have already been patented. But we cannot, in good conscience, ignore a limitation in the claims at issue based on that concern.

Claim 26 requires "a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter." According to the dissent, the inclusion of a "pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter," is merely intended use, and not a product limitation.

We have reviewed the case law relied upon by the dissent, and find <u>In re</u>

Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963), to be most relevant to the instant facts. As noted by the dissent in the discussion of that case, the court

refused to consider a method of curling hair using the claimed device, basically a hair curler, in determining the patentability of the claimed device. See id., 312 F.2d at 940, 136 USPQ at 459. The device itself, however, was drawn to "a core member for hair curlers comprising a body of elastically resilient foam material, the hair being wrapped directly on said body and said body carrying a hair waving lotion in non-liquid form distributed in the pores of the material." See id., 312 F.2d at 937, 136 USPQ at 458. We find that the claims at issue are most analogous to the claimed device, wherein the "core member for hair curlers comprising a body of elastically resilient foam material" being analogous to the "chamber" of instant claim 26, and the "hair waving lotion in non-liquid form distributed in the pores of the material" being analogous to the "the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum" of instant claim 26.

As to the "hair waving lotion," the court stated "[a]ppellants have never questioned that a hair curling composition, . . . can be provided in dry form.

Therefore no issue arises with reference to that matter." See id., 312 F.2d at 941, 136 USPQ at 459-60. From that statement, we infer that the court considered the limitation of the "hair waving lotion" in determining the patentability of the device, the "core member for hair curlers," and did not read it out of the claim by interpreting it as a statement of intended use. Similarly, in the instant case, "the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust

bean gum" is a limitation that must be considered in determining the patentability of the claimed device. We agree with the dissent that if the examiner found prior art teaching a device comprising "an output port," "a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum," and "an actuator coupled to the chamber" used for delivering, for example, insecticide, such prior art would anticipate the claimed device, as the recitation of delivery to a patient is intended use. We cannot, however, read the limitation of the presence of a pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum in the chamber of the claimed device as a statement of intended use.

The dissent asserts that we are therefore construing "the claim as being directed to a medicament, regardless of what container holds it." That assertion is incorrect, as we are reading the claim in its entirety, and thus any rejection over the prior art would have to address all of the limitations of the claims, i.e., "an output port," "a chamber containing the cohesive composite particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum," and "an actuator coupled to the chamber," and not just the pharmaceutically acceptable carrier. What we do not condone is reading a product limitation, i.e., "the medicament and the pharmaceutically acceptable carrier," out of a product claim simply by characterizing it as a statement of intended use. Instead, in our

opinion, every limitation positively recited in a claim must be given effect in order to determine what subject matter that claim defines. <u>In re Wilder</u>, 429 F.29 447, 450. 166 USPQ 545. 548 (CCPA 1970).

In dismissing the limitation to "the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum" as intended use, the dissent analogizes the device of claim 26 to "a bottle for delivering soda which comprises an output port for dispensing, a chamber, and a cap; wherein the chamber of the bottle contains a specified soft drink." Using that analogy, however, a kit claim drawn to a bottle for containing a specified DNA primer, in which the DNA primer is contained within the bottle, one would not have to consider the specified DNA primer in determining the patentability of the kit, as "the bottle does not change" no matter what is contained therein, whether it be water, a buffer, or nothing. Such a construction leads to a slippery slope, wherein any composition that is claimed as being in some sort of container would be merely considered a statement of intended use, as the container would not change as its contents changed. We agree with the dissent that terms that "merely set forth the intended use for ... an otherwise old composition ... do not differentiate the claimed composition from those known in the prior art." In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974). Thus, in the application of prior art, it would not matter if the label on the claimed device read for the treatment of a patient, or for use as an insecticidal spray. According to the court in Pearson, "[i]t seems quite clear

to us that one of the compositions admitted to be old by the appellant would not undergo a metamorphosis to a new composition by labeling its container to show that it is a composition suitable for [another use]." As stated by the court in <u>In re Zierden</u>, 411 F.2d 1325, 1329, 162 USPQ 102, 104 (CCPA 1969):

A mere statement of a new use for an otherwise old or obvious composition cannot render a claim to the composition patentable. As we said in <u>In re Lemin</u>, 51 CCPA 942, 326 F.2d 437, 140 USPQ 273, 276 (1964),

Appellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. 103. But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition. ... It seems to us that the composition ... would be exactly the same whether the user were told to cure pneumonia in animals with it ... or to promote plant growth with it (as here). The directions on the label will not change the composition....

However, as we understand this record, the facts before us on appeal are different from those in <u>Pearson</u>, <u>Zeirden</u>, and <u>Lemin</u>. In our opinion, the limitations drawn to the composition are positive claim limitations and cannot be read out of the claims a statement of intended use. Accordingly, we disagree with the dissent's characterization of the claims and treatment of the issues before us on appeal.

OTHER ISSUES

Upon return of the application, the examiner should consider the propriety of rejecting the pending claims under the judicially created doctrine of double patenting as being obvious over claims 1-20 of Baichwal.³

An obviousness-type double patenting rejection is properly used to reject claims to subject matter in a pending application that are different but not patentably distinct from the subject matter claimed in a prior patent. See In re Goodman, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015; see also In re Braat, 937 F.2d 589, 592, 19 USPQ2d 1289, 1291-92 (Fed. Cir. 1991). The rationale behind the rejection is that

[t]he public should . . . be able to act on the assumption that upon the <u>expiration</u> of the patent it will be free use not only the invention claimed in the patent but also the modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and prior art other than the invention claimed in the issued patent.

<u>In re Longi</u>, 759 F.2d 887, 892-93, 225 USPQ 645, 648 (Fed. Cir. 1985) (emphasis in original), citing <u>In re Zickendraht</u>, 319 F.2d 225, 232, 138 USPQ 23, 27 (CCPA 1963) (Rich, J. concurring).

Claim 1 of the Baichwal patent is drawn to (emphasis added):

A <u>respirable</u> particle-based pharmaceutical formulation <u>for</u> delivering a <u>medicament via insufflation</u>, comprising controlled release particles of a cohesive composite of a medicament and a pharmaceutically-acceptable carrier comprising xanthan gum and

³ U.S. Patent No. 6,387,394, issued May 14, 2002 (the '394 patent). Note that appellants have a second patent, U.S. Patent Number 5,612,053, issued March 18, 1997. Claim 1 of the '053 patent is drawn to a "respirable particle-based pharmaceutical formulation . . . comprising a polysaccharide gum 9of natural origin, wherein the average particle size . . is from about 0.1 to about 125 microns in diameter." The '394 patent is subject to a terminal disclaimer.

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locust bean gum wherein the average particle size of the said cohesive composite particles is from about 0.1 to about 125 microns in diameter.

Instant claim 26 differs from claim 1 of the '394 patent in that is explicitly recites the device required to deliver the respirable particle-based pharmaceutical formulation of claim 1 of the '394 patent. Appellants Appeal Brief, however, notes that commercially available devices are available. See Appeal Brief, page 7. In addition, the specification notes on page 20 that "[t]here are many devices described in the prior art which are useful for delivering a dose of powdered drug to the respiratory tract or naso-pharynx of a patient," and pages 20-25 of the specification describe such prior art devices. Thus, it would have been obvious to place the respirable particle-based pharmaceutical formulation of claim 1 of the '394 patent into one of the known prior art devices described into the specification to obtain the device claimed in instant claim 26.

FUTURE PROCEEDINGS

The case is being returned to the jurisdiction of the examiner for further action. The examiner may, however, wish to contact appellants' counsel before reopening prosecution to determine if filing a terminal disclaimer would resolve the above issues.

VACATED and REMANDED

Donald E. Adams

Administrative Patent Judge

Lŏrà M. Green

Administrative Paten Judge

BOARD OF PATENT

APPEALS AND

) INTERFERENCES

ELLIS, <u>Administrative</u> <u>Patent Judge</u>, dissenting.

In the case before us, I find several problems with the majority opinion all of which hinge on the manner in which they construe the claims. Here, I agree with the examiner's interpretation of the claimed device and therefore find that it is anticipated by the prior art. Thus, in my view, the rejection under 35 U.S.C. § 102(b) should be affirmed. Moreover, given my construction of the claims, it reasonably follows, that I do not agree with the majority that there is a double patenting issue. Therefore, I dissent for the following reasons.

As indicated by the majority above, the claims on appeal are directed to a device. See claims 26 and 43 on page 2 of the Decision.⁴ In construing the claims I find that the device comprises an output port, a chamber and actuator coupled to the chamber. The specification does not contain any figures of the device, but discloses (p. 20, lines 18-30) that

[t]here are many devices described in the prior art which are useful for delivering a dose of powdered drug to the respiratory tract or nasopharynx of a patient. . . . One such device is known as the Bespak device described in PCT publication WO 92/00771, hereby incorporated by reference, and available from Innovata Biomed Limited. The device described therein includes a storage chamber for storing a powdered drug to be administered and a metering member having metering cups in which individual doses of the powered drug are placed.

The specification further discloses that "[a]nother device for delivery of inhalation powders is described in U.S. Patent No. 2,587,215 (Priestly), hereby

⁴ The appellants state on page 4 of the main brief that there are two groups of claims; Group I consisting of claim 26-42, and Group II consisting of claim 43. For the prior art rejection; however, the appellants state argue claims 26-43 as a single group. Brief, p. 13. Therefore, I will limit my discussion to claim 26 which is representative of the subject matter on appeal.

incorporated by reference [id., page 21, lines 16-18]. . . . Yet another inhalation device suitable for delivering powdered inhalation drugs is described in U.S. Patent No. 4,274,403 (Struve), hereby incorporated by reference [id., lines 24-26]. . . . Another inhaler device is disclosed in U.S. Patent No. 4,524,769 (Wetterlin), hereby incorporated by reference [id., page 22, lines 26-27]." Numerous other prior art inhalers are described on pages 23-25.

I recognize that claim 26 sets forth the chamber as "a chamber containing the cohesive particles of the medicament and the pharmaceutically acceptable carrier, the pharmaceutically acceptable carrier comprising xanthum gum and locust bean gum, wherein the average particle size of said cohesive composite particles is from about 0.1 to about 125 microns in diameter." However, the chamber is still a chamber coupled to an actuator regardless of its content. The medicament described as being in the chamber is only an intended use of the device. In this regard the specification discloses a medicament, which comprises composite particles of a medicament and a pharmaceutically acceptable carrier wherein "the average particle size is from about 0.1 to about 10 microns in diameter for lung delivery. For nasal delivery, the average particle size is from about 10 to about 355 microns and preferably 10-125 microns."

⁵ The appellants' U.S. Patent No. 5,612,053 (the '053 patent) is directed to a "respirable particle-based pharmaceutical formulation," comprising controlled release particles and a pharmaceutically-acceptable carrier comprising a polysaccharide gum of natural origin, wherein the average particle size of the particles is from about 0.1 to about 125 microns in diameter. The appellants' U. S. Patent No. 6,387,394 (the '394 patent) is directed to a "respirable particle-based pharmaceutical formulation" comprising controlled release particles and a pharmaceutically-acceptable carrier comprising xanthan gum and locust bean

Page 4, line 35- page 5, line 1. The specification further discloses that "[t]he formulations of the present invention may be adapted for use with respect to any oral and/or nasal insufflation device for powdered or solid medicaments." Page 20, lines 7-9. In construing representative claim 26, I find that it is directed to a device whose intended use is for dispensing a medicament, such medicaments include one which comprises cohesive composite particles of a medicament and a pharmaceutically-acceptable carrier comprising xanthan gum and locust bean gum wherein the average size of the cohesive particles is from about 0.1 to about 125 microns in diameter. Thus, I find, and the appellants (Brief, pp. 10) and the majority (Decision, p. 7) agree, that the device recited in claim 26 (and claim 43) encompasses inhalers, which are well known in the art.

The majority states that they "can not find any authority, however, and the examiner does not cite to any such authority, that a claim can not be drawn to a device, in this case the inhaler, and the composition contained within that inhaler which are both drawn to the same statutory class of invention, i.e., a product." Decision, page 4-5. I disagree both with the majority's manner of construing the claims and their characterization of the examiner's position. As discussed above, representative claim 26 is directed to a device, in this case an inhaler, and the intended use of that inhaler to dispense a medicament. By means of a simple analogy, consider, for example, a claim which is directed to a bottle for

gum wherein the average particle size of the particles is from about 0.1 to about 125 microns in diameter. The '394 patent is subject to a terminal disclaimer. Thus, the appellants have two patents directed to the medicament described in representative claim 26.

delivering soda which comprises an output port for dispensing, a chamber and a cap; wherein the chamber of the bottle contains a specified soft drink, e.g., Fresca. Such a claim is not directed to two products. It is directed to the bottle, and the bottle alone. The bottle does not change if the chamber contains water, orange juice, or a different soda. It remains a bottle comprising an output port, a chamber and a cap.

The examiner's position is consistent with this construction of the claim.

The examiner is simply arguing that the medicament contained within the chamber does not place any further limitations on the device any more than would putting a label on the device.

The majority states that "the examiner is legally incorrect in his statement that '[c]omposition limitations can not be used to define the claimed device over that of the prior art." Decision, page 5. To the contrary, I find that the case law supports the examiner's position. See, e.g., In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (1963); In re Young, 75 F.2d 996, 25 USPQ 69 (CCPA 1935); Ex parte Thibault, 164 USPQ 666 (Bd. App. 1969).

In In re Casey, 370 F.2d 576, for example, the invention was directed to a machine for dispensing tape. Claim 1 in Casey read as follows:

1. A taping machine comprising a supporting structure, a brush attached to said supporting structure, said brush being formed with projecting bristles which terminate in free ends to collectively define a surface to which adhesive tape will detachably adhere, and means for providing relative motion between said brush and said supporting structure while adhesive tape is adhered to said surface [emphases added].

The prior art references were directed to (i) a device for perforating various types of sheet materials by use of needle-like pins wherein the sheet was supported by a rotary brush with open end bristles; (ii) a tape dispensing devise having a dispensing drum rotatably mounted on a supporting means wherein the drum supported fins to which adhesive tape was adhered; and (iii) an apparatus for dispensing tape which comprised several of the claim limitations. The Court held that the claims were obvious over the cited prior art. The Court was not persuaded by the appellants' arguments that the recitation in claim 1 of a "taping machine" and "the adherence of the adhesive tape to the surface formed by the free ends of the bristles of the brush," placed further limitations on the machine described therein. Rather, the Court agreed with the USPTO that these arguments were directed to "a method of handling adhesive tape, rather than the apparatus." The Court held that "[t]he claims in issue call for an apparatus or machine, viz, a tape dispensing machine. The manner of method in which the machine is to be utilized is not germane to the issue of patentability of the machine itself." Similarly, I find the appellants' argument (Brief, pp. 14-16) that the composition (the medicament) is a limitation on the claimed device, to be misguided. As disclosed in the specification, the claimed device encompasses prior art inhalers. Thus, the claimed device can be, and was, used to dispense known prior art medications. The medications placed in the device do not provide any new feature(s) to the device. In my view, the chamber containing

⁶ Moreover, I point out that if the appellants' reasoning is followed to it's logical conclusion, as it is in the majority decision, it would mean the device would be

medicament as recited in the claim sets forth an intended use, and does not bestow any further limitations, on said device.

The Court in <u>Casey</u> points out that its holding is consistent with In re Otto, 312 F.2d 937.

In Otto, the claims were directed to a device having a core member comprising a body of elastically resilient foam material with a non-liquid form of a hair waving lotion distributed in the pores of the foam material, and a method of making that device. The Court held that the device would have been obvious over the applied prior art. The Court stated [312 F.2d at 939] that

When the foam material dried, the pores remained impregnated with the hair waving lotion which would then become reactivated when water was added. Thus, the waving lotion imparted new properties to the foam material, and its addition was a step in the claimed method of making the core member of the device.

separately patentable every time a different medication is placed in the chamber.

7 Claim 1 was directed to:

^{1.} As a new article of manufacture, a core member for hair curlers comprising a body of elastically resilient foam material, the hair being wound directly on said body and said body carrying a hair waving lotion in non-liquid form distributed in the pores of the material.

⁸ The method of making the device involved saturating the body of elastically resilient foam material with a water-soluble solution of saponified hair waving lotion to impregnate the body. Claim 4 read as follows:

^{4.} The method of making a core member of the character described for hair curlers which comprises providing a body of elastically resilient foam material, saturating the body with a hair waving lotion consisting of a water-soluble solution of saponified material and thereafter permitting the saturated body to dry, whereby to produce a body the pores of which are substantially impregnated with a waving solution in non-liquid form adapted to be activated by subsequent wetting of the body.

... it should be remembered that the claims are directed to a particular device and a method of making that device, not to a method of curling hair wherein this particular device is used. It seems appellants are endeavoring to predicate patentability upon a certain procedure for curling hair using this device and involving a number of steps in the process. This process is irrelevant as is the recitation involving the hair being wound around the core insofar as the determination of whether these particular claims should be allowed or rejected.

The court cited In re Rishoi, 197 F.2d 342, 94 USPQ 71 (CCPA 1952) for the proposition that "inclusion of the material or article worked upon by a structure being claimed does not impart patentability to the claims." Here, I find that the medicament which is said to be in the chamber and dispensed by the claimed device recited in claim 26, like the hair in Otto, is "the material or article worked upon by [the] structure [device] being claimed [and, thus] does not impart patentability to the claims."

I do not agree with the majority that the hair waving lotion which impregnates that the foam material comprising the core of the claimed device in Otto is analogous to the medicament in the chamber. Rather, the hair waving lotion is an integral part of the claimed device which bestows new properties thereupon so that when the foam material is moistened, it exhibits new characteristics. In the present case, the medicament does not bestow any new properties on the claimed device. After the medicament is discharged, i.e., the device is put to its intended use, the device remains the same. There is no evidence of record that the medicament impregnates the device and imparts any new properties thereto. Or to use the words of the majority, the device recited in representative claim 26 does not "undergo a metamorphosis" when the

medicament is placed therein, citing <u>In re Pearson</u>, 494 F.2d at 1403. Thus, as discussed above, I find that the medicament is analogous to the hair in <u>Otto</u> as it is the material worked upon by the device.

I also find the majority's arguments with respect to the "kit" to be misguided. No where does the subject of a kit appear either in this case or in any of the case law relevant to the facts of this case. Moreover, the majority does not provide any facts that would place the kit, which they describe in context. That is, depending upon the facts of a particular case, and the majority clearly does not have one in mind since none is mentioned, the kit may or may not be patentable. In my view, it is the majority who are going down a slippery slope in a manner which obfuscates the facts of the case before us. It would be a simple matter to respond to the majority's alleged kit "analogy" by adding to or altering it in a manner to support my position, but I decline to exacerbate the situation by so doing.

I also find the majority's discussion of In re Pearson, 494 F.2d 1399 and In re Zierden, 411 F.2d 1325, to be misdirected. This discussion underscores their focus on the medicament; whereas, the claims in the case before us are directed to well known devices (inhalers) in which the medicament is placed. Other than In re Otto, 312 F.2d 937, the majority has not discussed the case law which pertains to devices or apparatuses which are not rendered patentable by reciting the material or article worked upon (because said material "does not impart patentability to the claims"). Attention is directed to In re Casey, 370 F.2d

576, In re Young, 75 F.2d 996, and Ex parte Thibault, 164 USPQ 666, discussed in this dissent. The majority's silence in this regard speaks volumes.

In re Young, 75 F.2d 996, is relevant to the facts of the case before us in that the claims were directed, inter alia, to a machine for making concrete beams which included said beams. The Court held that the machine itself was obvious over the applied prior art. With respect to the machine described in claim 6 of the application, the Court noted that it [claim 6] included a recitation of the material on which the machine worked (the concrete beams) and found that the inclusion of said material did not make the unpatentable machine patentable. In re Young, 75 F.2d at 998 ("we do hold that its [the material being worked upon] inclusion may not lend patentability, since the claim is not otherwise allowable"). Similarly, I find that the inclusion of the medicament to be dispensed does not render the presently-claimed prior art device patentable. The medicament is one type of material, which the presently claimed invention is capable of dispensing. Therefore, the medicament recited in claim 26 is the material on which the device works.

Finally, in <u>Ex parte Thibault</u>, 164 USPQ 666 (Bd. App. 1969), the claimed invention involved an apparatus for making formaldehyde. The merits panel of the Board of Appeals found that

[i]f the apparatus as claimed is not fully described in Walker (35 U.S.C. 102), it differs so little therefrom as to be obvious to the designer of the apparatus. The purpose to which the apparatus is to be put and the numerous expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.

That is, because the apparatus described in claim 12, had the same components as the applied prior art (a vaporizer, a heater, a condenser and a cold trap), the Board found that it was anticipated by the prior art. In the case before us, the appellants acknowledge that the claimed device is no different from those that exist in the prior art. See, the specification, pp. 19-25 and the Brief, pp. 7-10. It is immaterial which medicament is placed in the chamber and is dispensed, the device is still identical to the prior art inhalers. Thus, like the apparatus in Thibault, the device recited in representative claim 26 is anticipated by the prior art cited by the examiner and recited in the specification (In re Noyima, 509 F.2d 566, 571,184 USPQ 607, 611 (CCPA 1975)(work identified in the specification as prior art, may be treated as admitted prior art).

Needless to say, that because I construe the claims as being directed to a device which recites the material worked upon (i.e., a medicament that it is capable of delivering), I find no basis for the double patenting rejection suggested by the majority. I construe representative claim 26 as being directed to a device; whereas, the majority construes the claim as being directed to a medicament regardless of what container holds it [the medicament]. Moreover, even assuming, arguendo, that I did agree with the majority's construction of the claims, I find their comments with respect to a double patenting rejection lack a factual foundation. That is, the majority has not procured the parent and grandparent Baichwal patent applications to determine whether it is possible to make a double patenting rejection in this case. Thus, I do not understand why the issue is even mentioned. I point out that that double patenting rejections are

not permitted when the USPTO has made a restriction requirement. See 35 U.S.C. § 121 which states, in relevant part, that "a patent issuing on an application with respect to which a requirement for restriction under this section has been made or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them." Having raised this issue on a purely speculative basis, the majority should, in the very least, added a note of caution that there may be a statutory bar against such a rejection.

Since on this record I find that the prior art applied by the examiner anticipates the claimed device, I concur with the examiner's decision and would affirm the rejection.

DISSENTING

Joan Ellis

Administrative Patent Judge

) BOARD OF PATENT

APPEALS AND

) INTERFERENCES

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